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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/513,997	02/26/00	HARRINGTON J	5817-70

HM22/1107

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EXAMINER	
BRUNOVSKIS,P	
ART UNIT	**PAPER NUMBER**
1632	6

DATE MAILED: 11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/513,997	Harrington et al.
Examiner	**Group Art Unit**
Peter Brunovskis	1632

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

11/17/00
11/16/00

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *58-105* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *58-105* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 58-72, 77, 89, and 90, drawn to vectors and cells comprising such, classified in class 435, subclasses 320.1 or 325.

II. Claims 74 and 78, drawn to a method of producing an expression product in cultured cells, classified in class 435, subclasses 69.1 or 463.

III. Claim 75 drawn to a method of producing an expression product in vivo, classified in class 514, subclass 44.

IV. Claims 79, 80, 83-88, 92, and 100, drawn to a method for producing an expression product of an endogenous gene from cultured cells, classified in class 435, subclass 69.1.

V. Claim 81, 83-88, 92, 100, and 103, drawn to a method for overexpressing an endogenous gene in vivo, classified in class 424, subclass 93.21.

VI. Claim 82-88, 91, 92, 100, and 103, drawn to a method for overexpressing an endogenous gene in vivo, classified in class 424, subclass 93.21.

VII. Claim 91, drawn to a gene expression product, classified in class 530, subclass 350.

VIII. Claims 93-98 and 100, drawn to a method for producing an expression product in cultured cells, classified in class 435, subclass 69.1.

IX. Claim 99, drawn to a method for producing an expression product in cultured cells, classified in class 435, subclass 69.1.

X. Claims 104 and 105, drawn to a method for activating expression from an endogenous gene involving introduction of DNA breaks, classified in class 435, subclass 455.

Generic claims 83-88, 90, 92, and 100 are improperly drawn to distinct, misjoined inventions. The inventions are not proper species of a genus, since there are no common core structures, functions, or processes shared by the active compounds or methods used in independent or distinct inventions recited in the claims.

Claims 73, 76, 90, and 100 link(s) inventions II and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 73, 76, 90, and 100. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional

statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of groups II or III can be practiced with another materially different vector such as the vector of groups IV-VI, VIII or IX. Furthermore, the product of group I can be used in any of the methods of groups IV-VI, VIII or IX.

Inventions IV, V, and VI and invention VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process of inventions IV, V, and VI can be used to make a product of invention I. In addition, the product of invention VII can be made by a materially different

process comprising involving in vitro DNA manipulation such as PCR or by a similar method involving homologous recombination using related vectors comprising targeting sequences.

Inventions II and IV, inventions II and VIII, inventions II and IX, inventions IV and VIII, inventions IV and IX, inventions IX and invention VIII, inventions III and VI, inventions III and V, and inventions VI and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination inventions II, IV, and IX for use in vitro as claimed do not require for patentability the particulars of the various different transcriptional regulatory elements or amplifiable markers to which the claims in the respective subcombination inventions are drawn. Similarly, the combination inventions III and VI for use in vivo as claimed do not require for patentability the particulars of the various different transcriptional regulatory elements to which the claims in the respective subcombination inventions are drawn. Further, any one of subcombination inventions IV, V, VI, VIII, and IX can have separate utility by themselves or in other combinations involving other transcriptional regulatory sequences, for example.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of groups II, IV, VIII, and IX and group X because each of these methods comprises patentably distinct inventions since each of the methods involves different

vectors, different methods or modes of use, different technical considerations, different starting materials and/or different end products. Moreover, the the vector of group X does not require any of the particulars recited in the vectors of the other groups, such as unpaired splice donors or promoters, since the only particular required in e.g. the vector is a propensity to activate an endogenous gene. Therefore, claims 104 and 105 broadly embraces e.g. a vector merely possessing an enhancer sequence or encoding a cis-acting transcription factor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for Group I is not required for Groups II-X, and vice versa, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Brunovskis whose telephone number is (703) 305-2471. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Analyst, Patsy Zimmerman whose telephone number is (703) 308-8338.

Peter Brunovskis, Ph.D.
Patent Examiner
Art Unit 1632

Scott D. Priebe

SCOTT D. PRIEBE, Ph.D.
PRIMARY EXAMINER